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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,541	12/17/2001	Zhihong Helena Qi	CER-295	3561
20311	7590	03/23/2004	EXAMINER	
MUSERLIAN AND LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			KHARE, DEVESH	
			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,541

Applicant(s)

QI, ZHIHONG HELENA

Examiner

Devesh Khare

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's remarks filed on 10/10/03 are acknowledged.

Claims 1-8 are currently pending in this application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention of record.

The term "modified" is a relative term, which renders the claim indefinite. In the absence of the specific modifications to the compound claimed core or distinct language to describe the structural modifications or the chemical names of modified compounds claimed in all occurrences of this invention, the identity of said modified cyclodextrins would be difficult to describe and the metes and bounds of said modified compounds applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedges (Chem. Rev., 1998) of record.

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Claims 1-8 are drawn toward a process for forming a cyclodextrin(CD)-guest complex or increasing the amount of guest in cyclodextrin-guest complex, comprising forming a solution of cyclodextrin and a guest molecule in a solvent wherein the cyclodextrin is present at a concentration of 15% (w/w) or above, and the molecular ratio of cyclodextrin to guest is between 1:1 to 10:1, followed by mixing to form CD-guest precipitate and separating the precipitate to recover the complex. Additional claim limitations include a step of drying the precipitate, cyclodextrin is a modified cyclodextrin or an unmodified cyclodextrin, and solvent is water or an organic solvent, or a mixture.

Hedges teaches that the use of a variety of CDs for a very large number of applications is very well known in the art (see Table 1 on page 2038). Hedges discloses that in a complexation of CD-guest, the preferred molecular ratio of cyclodextrin to guest is 1:1 (see page 2035, 1st col. lines 24-27, 3rd para). The reference further teaches that a guest compound can be added into a solution of cyclodextrin in water to form a complex, which can then be collected as a precipitate, the collected precipitate can be dried (see page 2035, col.1 last para – col.2, 2nd para). Hedges discloses that the cyclodextrin concentration of 40-50% w/w can be used in a CD-guest complex (see page 2035, col. 2, last para). Hedges discloses that the amount of guest complexed with cyclodextrin can be increase or decrease in terms of its solubility in the complex (see page 2037, col. 2, 2nd para, lines 1-3). Hedges also discloses the modified and unmodified cyclodextrins and their effect in the solubility of the guest compound (see page 2037, 2nd col. 2nd para, mid-end and 3rd para, end part). The use of branched

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cyclodextrin is disclosed in the CD-guest complex on page 2038, 1st col., 3rd para.).

Hedges discloses an example of CD-Pilocarpine complex where cyclodextrin is used at a concentration of 15% (see page 2041, col. 1, last para). Hedges differs from the applicant's invention that Hedges does not teach the full range of cyclodextrin species types recited in claims 3 and 7. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the process of Hedges to increase the yield of a complex of cyclodextrin and guest and to increase the amount of guest complexed of claims 1 and 5 because the art teaches that a guest compound can be added into a solution of cyclodextrin in water to form a complex, which can then be collected as a precipitate. It would be further obvious to increase the yield of CD-guest complex or to increase the amount of guest complexed with cyclodextrin as taught by Hedges. Those skilled in the art would be motivated to obtain the CD-guest complex as the precipitate because this method is used to prove the feasibility of complexation of a particular guest to characterize the complex and to scale-up complexation using other methods (see page 2035,col.2, 2nd para, end part).

Rejection Maintained

Rejection of claims 3 and 7 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record.

Rejection of claims 1-8 under 35 U.S.C. 103(a) is maintained for the reasons of record.

Response to Arguments

Applicant's arguments filed on 10/10/03 traversing the rejection of claims 3 and 7 under 35 U.S.C. 112, second paragraph have been fully considered but they are not persuasive. Applicant has not addressed the chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the compound of matter claimed.

Applicants argue that "it is conventional in the field of cyclodextrin use and formation to refer to various types of cyclodextrin as modified, unmodified, branched or unbranched, etc". The skilled artisan knows modified means modified by the attachment of something (moiety) to a core. Applicant's claims fail to particularly point out such moieties. Metes and bounds of the moieties applicant intends can not be readily ascertained. The presence of the term "modified" in other document is noted. It is the deficiency in this application, which is at issue.

Applicant's arguments filed on 10/10/03 traversing the rejection of claims 1-8 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

Applicants argue, "the portion of Hedges referred to by the Examiner is in regard to the slurry method, not the precipitation method". Hedges discloses the precipitation method

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wherein a solution of cyclodextrin is made and the guest compound is added to the solution (see page 2035, first col., last para.). Furthermore, Hedges discloses that the cyclodextrin, which is in solution, forms complexes and the complex precipitates (see page 2036, first col., first para.).

Applicants argue, " there is no teaching or suggestion in Hedges to for a precipitate from a complex of cyclodextrin and a guest, where the cyclodextrin is present in a weight percent of about 15% or above." It is noted that Hedges discloses an example of cyclodextrin-pilocarpine complex wherein the cyclodextrin concentration is kept at 15% in a formulation to improve the ocular delivery (page 2041, first col. last para. and second col., first para.), therefore one skilled in the art would assume that a cyclodextrin-drug complex produced by the process of mixing the solution of cyclodextrin to a drug to form as a precipitate is useful for an improve ocular delivery.

2. THIS ACTION IS MADE FINAL. Final (necessitated by amendment due to new rejection (actually same rejection) over newly added claims). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

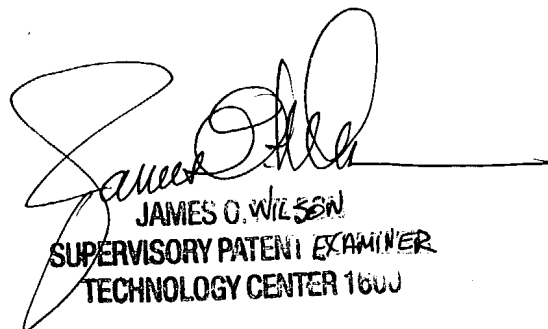
Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0653. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D., JD(3Y).
Art Unit 1623
March 19, 2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600